

**PHARMACY BOARD[657]**

**Adopted and Filed**

**Rule making related to registration of service programs**

The Board of Pharmacy hereby amends Chapter 5, “Pharmacy Support Persons,” and Chapter 11, “Drugs in Emergency Medical Service Programs,” Iowa Administrative Code.

*Legal Authority for Rule Making*

This rule making is adopted under the authority provided in Iowa Code section 147.76.

*State or Federal Law Implemented*

This rule making implements, in whole or in part, Iowa Code chapter 147A and Iowa Code sections 124.301 and 124.302.

*Purpose and Summary*

The amendments provide clarification for registration of service programs that are owned by and based at the same physical address of a hospital that is already registered with the Board for controlled substances. Also, the amendments provide updated references to and consistency with 657—Chapter 10 as a result of recent rule making by the Board.

*Public Comment and Changes to Rule Making*

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on October 11, 2017, as **ARC 3370C**. No public comments were received. No changes from the Notice have been made.

*Adoption of Rule Making*

This rule making was adopted by the Board on January 17, 2018.

*Fiscal Impact*

This rule making has no fiscal impact to the State of Iowa. This exception is expected to impact very few service programs, none of which are currently registered, therefore not increasing or decreasing any Board revenues.

*Jobs Impact*

After analysis and review of this rule making, no impact on jobs has been found.

*Waivers*

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

*Review by Administrative Rules Review Committee*

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

### *Effective Date*

This rule making will become effective on March 21, 2018.

The following rule-making actions are adopted:

ITEM 1. Amend rule 657—5.17(155A) as follows:

**657—5.17(155A) Tasks a pharmacy support person shall not perform.** A pharmacy support person shall not perform any of the following judgmental or technical functions. Performance of any of these tasks by a pharmacy support person shall constitute the practice of pharmacy without a license in violation of Iowa Code section 155A.7. A pharmacy support person shall not:

1. to 13. No change.

14. Assist with or witness the destruction or wastage of controlled substances pursuant to ~~657—subrule 10.18(2)~~ 657—subrule 10.22(2).

15. No change.

ITEM 2. Amend rule 657—11.3(124,147A,155A) as follows:

**657—11.3(124,147A,155A) Registration required.** In any service program which intends to provide services in or into Iowa that include the administration of controlled substances, the responsible individual shall ensure that each primary program site, regardless of location, is registered with the board pursuant to this rule. The current registration certificate shall be available at the primary program site for inspection and copying by the board, its representative, or any other authorized individual.

**11.3(1)** No change.

**11.3(2) Pharmacy-based service program.** In a pharmacy-based service program, the CSA registration shall be issued in the name of the service program and shall secondarily name the provider pharmacy. The CSA registration shall be issued for the address of the service program's primary program site and shall identify the pharmacist in charge of the provider pharmacy as the individual responsible for the controlled substances at the service program. A pharmacy-based service program that is owned by and physically located at the same address as an Iowa-licensed and -registered hospital may, but is not required to, obtain a separate registration.

**11.3(3)** No change.

**11.3(4) Change of address of registered primary program site.** A registrant ~~may~~ shall apply to change the address of the registered primary program site by submitting a ~~written request completed application and fee~~ as provided in ~~657—subrule 10.11(2)~~ 657—subrule 10.9(2). ~~The board and the DEA shall be notified in writing prior to a change of address of a registered primary program site.~~

**11.3(5)** No change.

ITEM 3. Amend subrule 11.26(2) as follows:

**11.26(2) Receipt and disbursement records in medical director-based service programs.** Any pharmacy or other authorized registrant that provides controlled substances for a medical director-based service program shall provide to the service program a record of the disbursement and maintain a record of the disbursement pursuant to rule ~~657—10.34(124,155A)~~ 657—10.16(124). The service program shall retain the record on which an authorized individual shall sign and record the actual date of receipt. The record shall include the following:

*a. to e.* No change.

ITEM 4. Amend rule 657—11.27(124,147A,155A) as follows:

**657—11.27(124,147A,155A) Ordering Schedule II controlled substances—medical director-based service programs.** Except as otherwise provided by ~~657—subrule 10.34(7)~~ 657—subrule 10.17(2) and under federal law, a DEA Form 222, preprinted with the address of the primary program site, is required to be maintained at the primary program site for the acquisition of each supply of a Schedule II controlled substance. The order form shall be executed only by the medical director named on the order form or by

an authorized signer designated pursuant to a properly executed power of attorney. A DEA Form 222 shall be dated and signed as of the date the order is submitted for filling. A medical director or authorized signer shall not pre-sign a DEA Form 222 for subsequent completion. All Schedule II order forms shall be maintained at the primary program site and shall be available for inspection and copying by the board, its representative, or any other authorized individual for a period of two years from the date of the record.

ITEM 5. Amend rule 657—11.33(124,147A,155A) as follows:

**657—11.33(124,147A,155A) Report of loss or theft of controlled substance.** Upon suspicion of any loss or theft of a controlled substance, the service director shall immediately notify the responsible individual. The responsible individual shall provide notice and reporting as required in rule ~~657—10.16(124)~~ 657—10.21(124).

[Filed 1/24/18, effective 3/21/18]

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 2/14/18.